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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/161,189	09/25/98	VALLEY	K 032-CP

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QM31/0810

EXAMINER

SERKE, C

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

08/10/00

Remail

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/161,109 09/25/98 VALLEY

K 032-CP

Q12/0107
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EXAMINER

KLINE, E

ART UNIT

PAPER NUMBER

3763

DATE MAILED:

01/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/161,109

Applicant(s)
Valley et al.

Examiner
Eric Kline

Group Art Unit
3763



☒ Responsive to communication(s) filed on Sep 25, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-100 is/are pending in the application.

Of the above, claim(s) 21-100 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: on page 75 line 17, the “guidewire lumen” is incorrectly referenced by numeral “879”.

Appropriate correction is required.

Claim 6 and 10 objected to because of the following informalities: claim has two “a” in a row. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is found to be indefinite because it is a duplicate of claim 6. It is unclear what the applicant wishes to claim because claim 10 fails to further limit the invention.

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Claim 12 is found to be indefinite because it is not clear how a "third lumen" can be set forth when a "second lumen" has not been previously claimed. Further, "a second opening" is merely inferentially included in the claim and not positively recited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1, 5, 6, 10, 12-20 rejected under 35 U.S.C. 102(b) as being anticipated by Jang, U.S. Patent 5,071,406. Jang discloses a catheter comprising an elongated shaft (44), an expandable means (42), expandable means being expandable eccentrically such that said expandable means has a first side (52) and a second side (64), said first side expanding to a larger size than said second size; wherein said expandable means comprises an inflatable elastomeric

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balloon (column 4, line 35); has a second inner lumen in fluid communication with balloon (54); a third inner lumen (Fig 12); expandable means having distal occlusive means (62) and proximal stabilizing means (42); wherein stabilizing means does not occlude the ascending aorta, does not block blood flow from the ascending aorta into the brachiocephalic artery (fig 7); distal portion of balloon of sufficient diameter to occlude the ascending aorta (52, 64)) and proximal stabilizing means comprises a proximal portion of said inflatable balloon of sufficient diameter to contact on inner surface of the ascending aorta (42); a region of reduced diameter between said distal portion and said proximal portion of said inflatable balloon (fig 7).

Claims 1, 5, 7, 9, 11, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kiyota et al., U.S. Patent 5,453,076. Kiyota et al. discloses a catheter comprising an elongated shaft (2), an expandable means (1), expandable means being expandable eccentrically such that said expandable means has a first side and a second side (fig 1), said first side expanding to a larger size than said second size; wherein said expandable means comprises an inflatable elastomeric balloon (column 5, lines 19-21); expandable means comprises an inflatable inelastic balloon (column 5, lines 29-40); inflatable balloon having at least a portion of second side of the inflatable balloon attached to said elongated shaft thereby restricting expansion of the second side (fig 1).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiyota et al. in view of Lee, U.S. Patent 5,619,993. Kiyota et al. disclose applicant's invention substantially as claimed. Kiyota et al. does not teach a preshaped distal portion configured to conform generally to the patient's aortic arch. Lee does teach a cardiovascular catheter designed for the use in the aorta. All the embodiments disclosed incorporate a preshaped, curved distal end. The shape of the curve being analogous to the specific site of the use of the device. Therefore, in view of the teachings, it would have been obvious to one of ordinary skill in the art to modify the Kiyota et al. catheter by providing its distal portion with a preshaped curve, as set forth in Lee, since the curve allows for the advantage of placement within the aorta.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,766,151. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-10 of application 09/161,109 contain the substantially the same limitations as claims 1-6 of patent 5,766,151.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Kline whose telephone number is (703) 305-7350. The examiner can normally be reached on Monday-Thursday from 8:00am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Coggins, can be reached on (703) 308-1344. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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June 21, 1999

Eric Kline

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WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER